

Nuclear Regulatory Commission

§ 63.141

may be changed by site characterization, construction, and operational activities.

(3) It monitors and analyzes changes from the baseline condition of parameters that could affect the performance of a geologic repository.

§ 63.132 Confirmation of geotechnical and design parameters.

(a) During repository construction and operation, a continuing program of surveillance, measurement, testing, and geologic mapping must be conducted to ensure that geotechnical and design parameters are confirmed and to ensure that appropriate action is taken to inform the Commission of design changes needed to accommodate actual field conditions encountered.

(b) Subsurface conditions must be monitored and evaluated against design assumptions.

(c) Specific geotechnical and design parameters to be measured or observed, including any interactions between natural and engineered systems and components, must be identified in the performance confirmation plan.

(d) These measurements and observations must be compared with the original design bases and assumptions. If significant differences exist between the measurements and observations and the original design bases and assumptions, the need for modifications to the design or in construction methods must be determined and these differences, their significance to repository performance, and the recommended changes reported to the Commission.

(e) In situ monitoring of the thermomechanical response of the underground facility must be conducted until permanent closure, to ensure that the performance of the geologic and engineering features is within design limits.

§ 63.133 Design testing.

(a) During the early or developmental stages of construction, a program for testing of engineered systems and components used in the design, such as, for example, borehole and shaft seals, backfill, and drip shields, as well as the thermal interaction effects of the waste packages, backfill,

drip shields, rock, and unsaturated zone and saturated zone water, must be conducted.

(b) The testing must be initiated as early as practicable.

(c) If backfill is included in the repository design, a test must be conducted to evaluate the effectiveness of backfill placement and compaction procedures against design requirements before permanent backfill placement is begun.

(d) Tests must be conducted to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale operation proceeds to seal boreholes, shafts, and ramps.

§ 63.134 Monitoring and testing waste packages.

(a) A program must be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program must be representative of those to be emplaced in the underground facility.

(b) Consistent with safe operation at the geologic repository operations area, the environment of the waste packages selected for the waste package monitoring program must be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program must include laboratory experiments that focus on the internal condition of the waste packages. To the extent practical, the environment experienced by the emplaced waste packages within the underground facility during the waste package monitoring program must be duplicated in the laboratory experiments.

(d) The waste package monitoring program must continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

§ 63.141 Scope.

As used in this part, *quality assurance* comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems,

or components will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 63.142 Quality assurance criteria.

(a) *Introduction and Applicability.* DOE is required by § 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities. The description must indicate how the applicable quality assurance requirements will be satisfied. DOE shall include information pertaining to the managerial and administrative controls to be used to ensure safe operation in its safety analysis report. High-level waste repositories include structures, systems, and components that prevent or mitigate the consequences of postulated event sequences or that are important to waste isolation capabilities that could cause undue risk to the health and safety of the public. The pertinent requirements of this subpart apply to all activities that are important to waste isolation and important to safety functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, site characterization, performance confirmation, permanent closure, decontamination, and dismantling of surface facilities.

(b) *Organization.* DOE shall establish and execute a quality assurance pro-

gram. DOE may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it.

(1) The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of:

(i) Assuring that an appropriate quality assurance program is established and effectively executed; and

(ii) Verifying that activities important to waste isolation and important to safety functions have been correctly performed by checking, auditing, and inspection of structures, systems, and components.

(2) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

(3) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to 10 CFR part 63 are being performed must